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09/920,118	07/31/2001	Rolf Menzel	10424-003	5780

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,118

Applicant(s)

MENZEL, ROLF

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36, 43 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36, 43 and 45-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/21/2003
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of an amendment, filed 5/6/2004, in which several claims were amended (claims 1, 3-4, 7-9, 11, 13-15, 18, 20-22, 25-27 and 31) and in which several new claims were added (claims 45-49). Claims 1-36, 43, 45-59 are pending and under consideration in the instant application.

Any rejection or objection of record not addressed herein is withdrawn. This action is not final as there are new grounds of rejection presented herein that were not necessitated by applicants' amendment of the claims in the response filed 5/6/2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-36, 43, 45-59 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These grounds of rejection are maintained for reasons of record in the previous office action mailed 11/6/2003 and which are repeated below.**

Claims 1 and 13 are both vague and indefinite in that the end result of the claimed method does not necessarily recapitulate the desired result recited in the preamble of the claim. The methods are directed to generation of a population of variant sequence modules, but there are no steps that clearly relate to the result of producing a population of variant sequence modules. For example, there is no clear and positive prior antecedent basis for the term "sequence module" in the last line of the claims as the term is not explained in the course of the

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methods. Similarly, there is no step or element of the claim that is clearly directed to a population of sequence variants. It would be remedial to amend the claim to include the elements of 1) what constitutes a sequence module, and 2) to include elements directed to a population of sequence variants.

Claim 43 is vague and indefinite in that the metes and bounds of the term “archived module” are unclear. The terms “module” and “archived module” do not appear to be well defined in the instant specification and are open to interpretation as to what structural compositions are encompassed by the claim. For example, would a representation of the sequence of the module archived on a computer disc be considered as an “archived module” produced by the methods of claim 1 or claim 13? Or is the term meant to specify only the physical polynucleotide structure produced by the methods? If the latter, then what are the structural ends of the polynucleotide that are comprised within the module?

Response to Arguments

Applicant's arguments filed in the response of 5/6/2004 have been fully considered but they are not persuasive. With regard to the end result of the methods recited in claims 1 and 13, the response essentially argues that the amendment of these claims to explicitly recite that which was inherent in the previous claims (i.e. the selection of bacterial cells that do not contain a negatively selectable marker, wherein said loss of the marker has occurred through homologous recombination between the donor vector and target vector). This is not found persuasive, even though the claims further recite the limitation “thereby generating a population of variant DNA molecules in bacterial cells”. The claims remain drawn to “a” donor vector that undergoes homologous recombination with a target sequence in a bacterial cell. It remains unclear how a

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single recombination event between what is apparently a single donor vector of a given type (i.e. having a single variant sequence) with a target sequence in a bacterial cell results in a population of variant DNA molecules. It would be remedial to amend the claim language to clearly indicate that the input donor vectors comprising different variant sequences flanked by the targeting sequences for recombination.

With regard to the metes and bounds of the term "archived module", the response essentially argues that the term is well and explicitly defined in the specification. While the specification does define the cited term, the definition provided at page 44 is not limiting in such a way as to provide a reasonable basis for the skilled artisan to know the metes and bounds of that which is recited in claim 43. It remains unclear whether applicants are claiming a sequence in the abstract (i.e. a sequence of polynucleotides) that has been archived in some manner (e.g. stored in a database), or whether the term applies only to an isolated nucleic acid. It would be remedial to amend the claim to clearly indicate which of the two choices is claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new rejection.

Claim 43 is directed to an “archived module” comprising a variant sequence produced by the method of claim 1 or claim 13. As indicated above, the metes and bounds of what is being claimed in the rejected claim are unclear with regard to whether the term applies to an actual, physical product, to an abstract sequence that has been stored in some manner or to both. In either case, the term appears to literally apply to *any* nucleic acid or its sequence that has been stored in some form or fashion and which has a “variant” sequence that could be produced by the methods of claims 1 or 13. There is no basis for the skilled artisan to envision the structural/functional characteristics of a given “archived module”. Therefore, given the incredibly huge genus of nucleic acids and their sequences that appear to be encompassed by the rejected claim, the skilled artisan would have reasonably concluded applicants were not in possession of the broadly claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 43 is directed to an “archived module” comprising a variant sequence produced by the method of claim 1 or claim 13. The specification teaches at page 44, section 5.4, the term “archived module” refers to a donor DNA sequence or target DNA sequence, whether or not the target sequence has undergone DGA or phenotype optimization, where the sequence comprising

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the archived module is known or has been demonstrated to encode a protein segment or domain that provides a particular function (e.g., ligand binding, enzymatic activity, structural activity), and has been stored and catalogued (archived), e.g., for future use, such as future use in similar or different DNA situations. As indicated above, the metes and bounds of what is being claimed in the rejected claim are unclear with regard to whether the term applies to an actual, physical product (e.g. a nucleic acid molecule), to an abstract sequence that has been stored in some manner or to both. In either case, the term appears to literally apply to *any* nucleic acid or its sequence that has been stored in some form or fashion and which has a "variant" sequence that could be produced by the methods of claims 1 or 13.

Claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by Russo et al (U.S. Patent No. 5,985,598 A; see the entire patent). **This is a new rejection.**

Russo et al teach the identification of the TCL-1 gene sequence (SEQ ID NO: 1) and the protein it encodes (SEQ ID NO: 2). Russo et al thus exemplify the isolation and "archiving" of a nucleic acid and its sequence that comprises "variant" sequences that could be generated by the methods of claim 1 or claim 13. Therefore, Russo et al anticipate the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

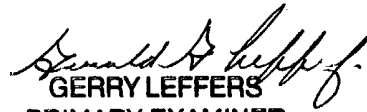
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

ggl


GERRY LEFFERS
PRIMARY EXAMINER